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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,557	01/03/2002	Terry M. Fredeking	7841P001	8399

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,557	FREDEKING ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 10/10/2006. Claim(s) 1-12 have been cancelled. Claim(s) 13-26 are pending and examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-26 are rejected under 35 U.S.C. 103(a) as being obvious over Golub et al. (US Patent 6,015,804).

Golub et al. teach that tetracycline increases the endogenous levels of IL-10 in mammals, which is useful in reducing the levels of IL-1 and TNF-alpha (see abstract). IL-10 can be administered to treat diseases or conditions, such as inflammation, diabetes, cancer, graft versus host disease, inflammatory bowel disease, arthritis, autoimmune disorders, and rheumatoid arthritis (col. 2, lines 6-18). Furthermore, IL-10 is produced by cells present in the blood (col. 4, lines 59-64), either in vivo or in vitro (col. 5, lines 54-55). Density gradient centrifugation was used to isolate the blood (examples 1-2). Upon centrifugation, blood is inherently separated into fractions containing globulin, anti-hemophilia factor, albumin, serum, and plasma.

Examiner views the limitations regarding the increase of cytokine receptors as properties of the process of making the composition. "Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Furthermore, the list of diseases are considered preamble and also will not be given any patentable weight. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the

claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

Golub et al., however fails to disclose a specific isolation step of the blood.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to isolate the blood by density gradient centrifugation in a separate step.

A person of ordinary skill in the art would have been motivated to isolate the blood by density gradient centrifugation because of the expectancy to isolate and increase the amount of blood containing increased cytokine receptors to be used for therapeutic means.

Response to Arguments

Applicant argues that the Golub et al. reference is directed to a method of increasing cytokines, not cytokine receptors as claimed, even though the same tetracycline derivatives are disclosed to be administered.

This is not persuasive because cytokine receptor production will inherently occur when a patient is given the same tetracycline derivatives. It is applicant's burden to show that the claimed functional properties of tetracyclines will not occur in the situation as disclosed by Golub et al.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

It is well known in Patent Law that if applicants are claiming a biological pathway as the basis for their invention then a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated, and the effect are the same. An

explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompasses by the claims.

Applicant's arguments herein are related to the mechanism of action of an agent in the treatment. Note that the mechanism of action of an agent in the treatment, by itself, does not have a bearing on the patentability of the invention if the method steps are already known even though applicant has proposed or claimed the mechanism. Applicant's recitation of a new mechanism of action for the prior art method *will not, by itself, distinguish* the instant claims over the prior art teaching the same or nearly the same method steps.

Applicant also argues that Golub et al. does not teach isolation of the blood or a fraction thereof for a composition for the treatment of a disease, condition, or disorder. This is not persuasive because Golub et al. clearly teach increasing IL-10 in examples 1 and 2, which are also taught to treat diseases or conditions, such as inflammation, diabetes, cancer, graft versus host disease, inflammatory bowel disease, arthritis, autoimmune disorders, and rheumatoid arthritis (col. 2, lines 6-18). Golub et al. disclose that the following examples are provided to assist in further understanding the invention and are intended to be further illustrative of the invention and are not limiting upon the reasonable scope thereof (col. 9, lines 15-19). Therefore, the motivation to modify Golub et al. to isolate the blood by density gradient centrifugation is because of the expectancy to isolate and increase the amount of blood containing increased cytokine receptors to be used for therapeutic means. It is this blood and its usefulness for treating various disease conditions, where the motivation lies to introduce a specific

isolation step. The examples teach blood isolation and processing methods by disclosing density gradient centrifugation. Thus, a person of ordinary skill in the art would have been motivated to isolate the blood by density gradient centrifugation because of the expectation of success in isolating and increasing the amount of blood containing increased cytokine receptors to be used for therapeutic means.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER